

Attorney Docket No.: WARF-0002
Inventors: Laughon, Allen S.
Serial No.: 09/810,385
Filing Date: March 16, 2001
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REMARKS

Claims 1-4 are pending in the instant application. Claims 1-4 have been canceled. Claims 9-12 have been added. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §112

Claims 1-4 remain rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not disclosed in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention has been maintained. The Examiner alleges that there is no support for a TGF-beta-dependent promoter, expressing interacting proteins and repression of said reporter. Applicant respectfully disagrees with this rejection.

MPEP 2163.02 quite clearly indicates that in order to comply with the written description requirement, the subject matter of the claim need not be described literally, *i.e.*, using the same terms or *in haec verba*. What is required is that Applicant show possession of what is claimed. In viewing the whole of Applicant's disclosure, the written description requirement has been met. For example, Applicant discloses in the passage between page 14, line 11, and page 15, line 12, the principle of the claimed method, namely the identification of proteins or small molecules that interact with Smad proteins to prevent interaction of CtBP with Smads or DNA-binding Smad co-repressor proteins, or to prevent formation of a DNA-bound complex containing a Smad protein, CtBP protein and DNA-binding Smad co-repressor protein,

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thereby preventing repression of genes that are negatively regulated by TGF- β signaling pathways. As one embodiment, the assay is carried *in vivo* with a reporter protein having a TGF- β -dependent reporter. In this regard, Applicant has exemplified the required elements of the claimed cell-based assay at pages 9 and 10. This disclosure teaches lacZ reporter constructs transfected into *Drosophila* cells and co-expressed with Schnurri (a DNA-binding Smad co-repressor protein) and Smads, Mad and Medea, which interact and repress transcription of the reporter. Furthermore, page 10 (lines 10-12) teaches that the repression of lacZ in transfected cells was enhanced by co-expression of dCtBP. It is clear from this disclosure that in order to achieve repression of the reporter, the Smad protein, CtBP protein and DNA-binding Smad co-repressor protein must be co-expressed by the cell being assayed. Thus, in contrast to the Examiner's suggestion, Applicant's disclosure clearly supports expressing interacting proteins and repression of the reporter.

Moreover, Applicant respectfully disagrees with the Examiner's suggestion that the specification lacks support for a TGF-beta-dependent promoter. Applicant teaches at pages 1-3 that it is well-known in the art that TGF-beta, activin and bone morphogenetic protein signals regulate the expression of genes such as c-myc, cyclin, collagen proteases, and wingless. Furthermore, Applicant exemplifies reporter constructs containing promoters (e.g., the wingless promoter), which are regulated by such signals, in cell-based assays, wherein cells of the assays co-express interacting proteins comprising a Smad protein, a DNA-binding Smad co-repressor protein and a CtBP protein. See pages 9 and 10. Accordingly, in an earnest effort to place the claims in

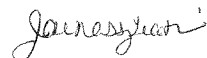
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better form for consideration and allowance, Applicant has canceled claim 1-4 and presents new claims 9-12 which clarify the nature of the promoter and expression of the claimed elements. Support for new claims 9-12 is found in canceled claims 1-4, pages 1-3, pages 9-10, and pages 14-15 at passages recited herein. In light of this amendment and accompanying remarks, Applicant respectfully believes that the written description requirement has been met. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

II. Conclusion

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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